SEP - 7 2000

K001342

510(k) Summary

1. **Submitter:**

Post Operative Pain Management (Inc) LLC
1 Corporation Center
Broadview Heights, OH 44147

Tel: 440-526-5104
Fax: 440-526-0158

2. **Contact:**

Charles Rowland II
Regulatory Affairs and Product development
Post Operative Pain Management (Inc) LLC

3. **Date Prepared:** April 27, 2000

4. **Device Trade Name:** P.O.P. Kit
Common Name: Various

5. **Predicate Device(s)**

Sgarlato PCIP	(K896422)
Pain Buster	(K980558)

6. **Description**

The P.O.P.™ Kit is a group of products that function as a system for the administration of pain medication directly into a surgical wound.

7. **Intended Use**

A) Sole use is for the administration of pain medication subcutaneously.
B) For use up to 24 hours or institutional protocol.
C) For single patient use.

8. **Comparison to predicate device(s)**

The P.O.P.™ Kit offers identical technique, usage parameters and intended use to the predicate device(s). The elastomeric membrane delivers fluid at a controlled rate and manner the same as the Predicate devices.

9. **Non-clinical Test Summary**

All kit components are currently individually available for distribution via 501(k).

10. **Conclusion**

The P.O.P.™ Kit is substantially equivalent to the products currently being legally marketed by Sgarlato Labs and I-Flow Corporation.

SUMMARY OF SAFETY AND EFFECTIVENESS

April 27, 200

Trade Name: P.O.P. Post Operative Pain Kit

Commmon Name: Elastomeric Infusion Pump Kit

Classification Name: Pump,Infusion, Elastomeric

All questions and/or comments concerning this docuement should be made to:

Charles Rowland II
Regulatory Affairs and Product Devolpment

Post Operative Pain Maugement (Inc.) LLC
1 Corporation Center
Broadview Heights, OH 44147

Telephone: 440-526-5104
Fax: 440-526-0158

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2000

Mr. Charles Rowland II
Regulatory Affairs and Product Development
Post Operative Pain Management, Incorporated
One Corporation Center
Broadview Heights, Ohio 44147

Re: K001342
Trade Name: P.O.P Pain Kit
Regulatory Class: II
Product Code: MEB
Dated: July 31, 2000
Received: July 31, 2000

Dear Mr. Rowland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K001342

DEVICE NAME : P.O.P. Pain Kit

INDICATIONS FOR USE:

Indications:

The system is indicated for the relief of pain by the administration of analgesics into the intra-operative site.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRANCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use X OR Over-The-Counter-Use _____

(Per 21 CFR 801.109) (Optional Format 1-2)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
Number K001342